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## (54) IMPLANTABLE HEART PACEMAKER

(71) We, SIEMENS AKTIENGESELLSCHAFT, a German company, of Berlin and Munich, Germany, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to an implantable heart pacemaker for supplying electrical stimulation pulses to stimulate heart action.

The operation time of a battery-operated implantable heart pacemaker is restricted by the capacity and, consequently, for a given consumption of energy, by the service life of the available batteries. This makes it, in practice, necessary to replace the heart pacemaker or the batteries thereof at relatively short intervals of time of approximately 3 to 4 wears. Since this can be effected only by operation and, additionally, only with a risk to the patient, it is accordingly desirable to achieve an increase in the service life of pacemaker batteries. Even an increase in the service life of 20—50% (amounting, in conventional batteries, to an increase in working time of approximately 1—2 years) would, under the given circumstances, be of significant value.

It is therefore not difficult to understand why, from the commencement of the development of the heart pacemaker, the attempt has been made to employ for the operation of the pacemaker sources of electrical energy which, whilst exhibiting the smallest possible dimensions and affording a high degree of operational reliability, have a large capacity and consequently a long service life. Consequently, endeavour has been concentrated on either developing entirely new sources of electrical energy, for example such as are based on the atomic principle, or improving the batteries already available. Whereas the former mode of approach has hitherto not yielded any considerable success, it has nevertheless been possible with the latter mode of approach to develop new types of batteries, the so-called lithium cells, which as compared with the conventional batteries have a greatly reduced natural or intrinsic current consumption and therefore permit the achievement of increased service life. Success has been partial, however.

In accordance with the above remarks, the invention is based mainly on the problem of how to provide a heart pacemaker which is fed by batteries of commercially-available types but which has, as compared with hitherto employed battery-fed pacemakers, a considerably increased service life which may be 2—15 times longer.

The invention proceeds from the realisation that the mode of operation of battery-operated heart pacemakers known to us is uneconomical from the aspect of energy consumption, since the pacemakers operate during their entire duration of operation with a pulse strength which is so fixed at a maximum value that even at the maximum heart stimulation threshold the action of the heart is reliably stimulated. However, it has been found that the stimulation threshold at which a stimulation pulse of the pacemaker initiates the action of the heart is subjected to considerable fluctuation not only from one patient to another but also during the time, lasting many years, of use of the heart pacemaker. Thus the invention aims at matching the voltage (and therewith the current strength) of the stimulation pulses emitted by the pacemaker to the particular stimulation threshold value, in such manner that the voltage of the pacemaker pulses is for the most part located only a little above the prevailing value of the stimulation threshold.

According to the present invention, there is provided an implantable heart pacemaker operable with a predetermined maximum battery voltage, comprising pulse-generating circuitry for supplying electrical stimulation pulses to stimulate heart action, a detector for sensing whether such heart action is stimulated by successive stimulation pulses, and pulse-control circuitry arranged to control the pulse-generating circuitry, in dependence upon the detector, so that, if successive stimulation pulses each stimulate such heart action, such successive pulses are supplied at

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respective pulse voltages which are successively less, but so that if one of the stimulation pulses fails to stimulate such heart action within a predetermined period immediately following the supply of that one pulse and ending before the next stimulation pulse is supplied, the said next stimulation pulse is supplied at a pulse voltage greater than that of the said one of the stimulation pulses by an amount which, whilst sufficient for the said next stimulation pulse to stimulate such heart action, is small in relation to the said maximum battery voltage.

Preferably, the amount by which the pulse voltage of a stimulation pulse, immediately succeeding a stimulation pulse which failed to stimulate the required heart action, is greater than the pulse voltage of the preceding stimulation pulse is in the range from 0.1 to 0.5 volts.

Preferably, the pulse-control circuitry of a heart pacemaker embodying the invention is adapted to respond to heart action on the basis of the QRS pulses triggered by the action of the heart. In this case, the detector of the pacemaker is adapted to sense such QRS pulses and the pulse-control circuitry is adapted to control the pulse voltage of the electrical stimulation pulses such that if no QRS pulse is sensed, within the abovementioned predetermined period, following the supply of an electrical stimulation pulse by the pacemaker, the next electrical stimulation pulse supplied thereby is supplied at a pulse voltage greater than would otherwise have been the case.

Thus, in a heart pacemaker embodying the invention, the voltage of the stimulation pulses can be so controlled, during the entire time of utilisation of the pacemaker, as a function of the varying stimulation threshold of the heart, that the pulse voltage is, without danger to the patient, reliably adapted to a value which is as far as possible close above the threshold value, the pacemaker supplying to the heart, in the form of stimulation pulses, at least approximately only that energy which is just necessary for maintaining the action of the heart. In this manner, there can be achieved as a function of the stimulation threshold, in contradistinction to what takes place with battery-fed pacemakers known to us, an average increase in the service life of the battery and therewith of the pacemaker by the factor 2—15. In this way, it becomes possible, using the available batteries (preferably lithium cells) not only to lengthen the operating life of the pacemaker considerably but also to increase it to such an extent that, in many cases, replacement of the pacemaker (or batteries therefor) and the operation necessary for this purpose may be superfluous. Since, in a heart pacemaker embodying the invention, the pacemaker stimulation pulses can be approximately matched to the prevailing value of the stimulation threshold, so that over-stimulation during relatively long periods of time is avoided, the danger of the induction of ventricular fibrillation during the vulnerable phase can be avoided.

The electronic control of the stimulation pulse voltage is therefore effected, in an embodiment of the invention incorporating a QRS-pulse detector, as a function of the activity of the heart, in such manner that if the heart action fails and, therewith no QRS pulse (check-back pulse) is supplied, the voltage of the following stimulation pulse is increased to such an extent that it exceeds the stimulation threshold value, thereby bringing about contraction of the heart. At the same time however, the amount by which the voltage of this following stimulation pulse is greater than the voltage of the preceding pulse is small in relation to the maximum battery voltage used to operate the pacemaker. The stimulation pulse voltage is controlled so that the pulse voltage of successive stimulation pulses decreases from a maximum value (generally approximately 4 to 7 volts) in small stages until it falls below the stimulation threshold value and a QRS pulse (check-back pulse) is not emitted, whereupon the stimulation pulse voltage is once again stepped-up above the stimulation threshold value. Thus, in such a pacemaker automatic correction of the pulse voltage of the stimulation pulses is effected as a function of the particular stimulation threshold at any time.

Generally, with a pacemaker embodying the invention the rate at which stimulation pulses are supplied thereby is determined by a pulse train produced by a battery-operated pulse generator forming part of the pulse-generating circuitry of the pacemaker. Such a pulse train may be employed to control the operation of discharge control means of the pulse-generating circuitry so that a pulsing capacitance thereof under the control of the discharge control means is discharged successively, at a repetition rate determined by the pulse repetition rate of the pulse train from the generator, thereby to produce a train of stimulation pulses. So that successive stimulation pulses may be of progressively decreased strength, the pulsing capacitance may be arranged to be charged by a charging capacitance itself charged by suitable charging means, viz. the pacemaker batteries, the value of the charging capacitance being greater than that of the pulsing capacitance. The pulsing capacitance can then be alternately discharged by the discharge control means and charged by the charging capacitance at the pulse repetition rate of the pulse train from the generator, the charging capacitance itself not being recharged, having previously been charged

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from the charging means, until, because of the progressive drop in voltage accompanying successive discharge of the charging capacitance, that voltage and consequently the voltage of the pulsing capacitance fall below the stimulation threshold value. When this stage is reached the charging capacitance is charged by the charging means so that the next stimulation pulse produced by the next discharge of the pulsing capacitance has a voltage above the stimulation threshold value. To achieve this, the pulse-control circuitry of the pacemaker may include current blocking means connected between the charging means and the charging capacitance and arranged under the control of the QRS-pulse detector referred to above. Thus, when the stimulation pulse voltage falls below the stimulation threshold value prevailing at the time in question no QRS pulse (check-back pulse) is sensed within a predetermined period within which such a QRS pulse would normally have been expected; accordingly, the current blocking means, which previously inhibited charging of the charging capacitance by the charging means, are caused, in response to the absence of the QRS pulse, to permit recharging of the charging capacitance for a controlled period of time. It is advisable to select the value of the charging capacitance to be approximately 20 to 100 times greater and, preferably, 40 to 80 times greater than that of the pulsing capacitance.

The current blocking means may comprise a monostable multivibrator and a bistable multivibrator that respectively have inputs connected to receive the pulse train from the pulse generator and respectively have outputs connected to inputs of an electronic gate arranged to control the connection of the charging means to the charging capacitance in dependence upon input signals which the gate respectively receives at its inputs from the multivibrators, the bistable multivibrator having a further input connected so as to receive a pulse every time a QRS pulse is sensed by the detector. The detector may comprise a receiver, for example a heart probe, for receiving QRS pulses and, connected therewith, an amplifier for delivering the received QRS pulses in amplified form at an output thereof; the further input of the above-mentioned bistable multivibrator can then simply be connected to the output of the amplifier. As a means of ensuring that the amount by which the pulse voltage of a stimulation pulse, following a stimulation pulse which failed to stimulate heart action, exceeds the pulse voltage of the preceeding stimulation pulse is small in relation to the maximum battery voltage, a resistance may be connected between the charging capacitance and the electronic gate so that this capacitance is charged from the battery voltage through this resistance. The time constant of the monostable multivibrator is expediently approximately 150 to 250, and preferably 170 to 220, milliseconds, so that the monostable multivibrator does not supply, at its output, a triggering signal to the gate until a triggering signal emitted by the bistable multivibrator in response to a QRS pulse becomes effective on the gate.

A heart pacemaker embodying the invention may be constructed as a demand pacemaker without any noteworthy additional outlay. For this purpose, such a pacemaker has a pulse generator which is connected so that the operation thereof is controlled in dependence upon whether or not successive QRS pulses are respectively sensed by a QRS-pulse detector of the pacemaker within a predetermined period immediately following the supply of respective successive stimulation pulses by the pacemaker; further, the pacemaker in this case has a charging capacitance which in addition to its other connections is connected to the above-mentioned charging means through a high resistance (for example of the order of tens of megohms, say 30 M Ω) so as to prevent the voltage across the charging capacitance from falling off in the event of a relatively long interruption of heart action stimulation. Where the detector includes an amplifier such as mentioned above, the output thereof can for example be connected by a control line to a control input of the pulse generator, thereby to provide a feedback line for switching in the generator if no QRS pulse is received within the predetermined time interval.

For a better understanding of the invention, and to show how it can be carried into effect, reference will now be made, by way of example, to the accompanying schematic circuit diagram of an implantable heart pacemaker embodying the invention.

The illustrated heart pacemaker has a pulse generator 10 which is adapted to supply a pulse train at a pulse repetition rate of 70 pulses per minute from an output $A_1$, the pulses of the train being square wave pulses having a pulse duration of 1 msec. The pulse generator 10 is driven by a battery, preferably a lithium battery, providing a maximum battery voltage of 6 volts. For this purpose, current supply inputs $E_1$ and $E_2$ of the generator 10 are connected to operating battery voltages of 1.5 and 6 volts respectively. The output $A_1$ of the pulse generator 10 is connected *via* a series resistance 11 to the base of a control transistor 12 in the emitter-collector circuit of which there is connected a stimulation or pulsing capacitance 13 of for example 5 μF. The emitter-collector circuit of the transistor 12 is thus rendered conductive for a short period by successive pulses from the pulse generator 10. The pulsing

capacitance 13 is connected to a heart probe 14 which, in operation of the pacemaker, is applied to a heart to be stimulated. When the transistor 12 is rendered conductive the capacitance 13 discharges *via* the probe 14 and the transistor 12; a stimulation pulse is accordingly applied to the heart at a voltage depending upon the voltage across the capacitance 13. Thus as successive pulses are generated by the generator 10, stimulation pulses are applied successively to the heart at the same rate as the generator pulses are emitted.

Connected with the capacitance 13 is a charging capacitance 15 the value of which is substantially larger than that of the capacitance 13 and is, in this case, for example 330μF. The charging capacitance 15 charges the pulse capacitor 13 *via* a resistance 16 of for example 6 kilohm, in each interval between two successive stimulation pulses, *i.e.* every time the emitter-collector circuit of the transistor 12 connected in the discharge circuit of the capacitance 13 is rendered non-conductive.

The heart pacemaker is provided with a second probe 17, connected to the heart, *via* which QRS pulses produced when the heart is active are sensed as check-back or revertive signals. The probe 17 is connected to an electronic amplifier 18 having current inputs $E_1$ and $E_2$ connected to battery voltages of 1.5 and 6 volts respectively. In the amplifier, the QRS pulses are amplified in stages to a voltage of 6 volts and delivered at an output $A_3$. The output $A_3$ of the amplifier 18 is connected to one input $I_1$ of a bistable multivibrator 19 having an input $E_2$ connected to an operating voltage of 6 volts, a second input $I_2$ of this multivibrator being connected to an output $A_2$ of the pulse generator 10. Also connected to the output $A_2$ is one input E of a monostable multivibrator 20 having a further input $E_2$ connected to a battery voltage of 6 volts. The bistable multivibrator 19 and the monostable multivibrator 20 respectively have outputs A and $\bar{A}$ which are respectively connected to control inputs $X_1$ and $X_2$ of a NOR gate 22 having an output $X_3$ connected to a charging line 21 for the charging capacitance 15, an input $E_2$ of the NOR gate 22 being connected to an operating battery voltage of 6 volts. Connected between the capacitance 15 and the output $X_3$ are a diode 23 and a resistance 24 the resistance value of which is larger than that of the resistor 16, being for example between 6 and 22 kΩ and, preferably, 12 kΩ.

The mode of operation is as follows:

The pulse generator 10 supplies, at its output $A_2$ as well as its output $A_1$, control pulses at the pulse repetition rate of, in this case, 70 pulses per minute. Each control pulse at the output $A_1$ trips the transistor 12, so that the pulsing capacitance 13 discharges and, thereby, applies a stimulation pulse *via* the probe 14 to the heart.

The stimulation pulse voltage is a function of the voltage at the charging capacitance 15, which falls off with increasing discharging until the voltage at the pulsing capacitance 13 and therewith the voltage of the stimulation pulses has reached a value which is below the stimulation threshold of the heart and therefore triggers no heart action. In this case, no QRS signal can be received *via* the heart probe 17. The result of this is that, *via* the multivibrators 19 and 20, the gate 22 is reversed and therewith the charging capacitance 15 is charged *via* the diode 23 and the resistance 24 from the battery voltage of 6 volts. The voltage at the capacitance 15 and consequently also at the capacitance 13 is thus once again increased sufficiently for the next stimulation pulse to be above the stimulation threshold.

The pulse generator 10 supplies, *via* its output $A_2$, square-wave pulses to the monostable multivibrator 20, so that with each pulse a positive voltage is applied to the input E of this multivibrator, which has a time constant of 200 msec. Thus, after expiry of a delay time of 200 msec, the multivibrator 20 supplies a negative pulse at the output $\bar{A}$ and therewith to the input $X_2$ of the gate 22. Simultaneously, the square wave pulses are supplied to the input $I_2$ of the bistable multivibrator 19, so that for each such pulse a negative voltage is established at the output A of the bistable multivibrator, and therewith at the input $X_1$ of the gate 22, provided that there is no amplified (6 volt) QRS-pulse at the input $I_1$ of the bistable multivibrator 19. In this latter case, the multivibrator 19 is so triggered that a positive potential builds up at its output A.

The delay time of 200 msec corresponds to the maximum time interval between a stimulation pulse and the heart action triggered thereby. If, within 200 msec after emission of a pulse at the outputs $A_1$ and $A_2$ of the pulse generator 10, no heart action takes place and thus no QRS-pulse is received by the probe 17, then both inputs $X_1$ and $X_2$ of the gate 22 become negative, *i.e.* the output $X_3$ of the gate becomes positive. Thus, the gate is so triggered that, then, the charging capaci- The series-connected resistance 24 is to dimen- The series-connected resistance 24 is so dimensioned that on the gate being triggered in consequence of the fact that there is no QRS pulse, the voltage at the capacitance 15 is increased only by a relatively small value of for example 0.1 — 0.5 volt, although the voltage increase is sufficient to raise the following stimulation pulse above the stimulation threshold. Thus, charging of the capacitance 15 is effected, with each heart action

which does not take place, by a step of for example approximately 0.1 to 0.5 volts. Consequently, the pulse voltage of the stimulation pulse following a stimulation pulse which failed to stimulate heart action will be greater than the pulse voltage of the preceding stimulation pulse by an amount (e.g. 0.1 to 0.5 volts) which is small in relation to the maximum battery voltage of 6 volts from which the capacitance 15 is charged by way of the gate 22 and the line 21 when the gate is open.

The QRS pulse at the input $I_1$ of the bistable multivibrator 19 has the effect that the output A thereof becomes positive and, therewith, the gate 22 remains blocked. Thus, the QRS pulse suppresses the change-over of the gate 22 and, consequently, the voltage increase in the charging capacitance 15. (In the absence of such a QRS pulse, the simultaneous appearance of the signal supplied by the pulse generator to the input $I_2$ of the bistable multivibrator 19 and the signal of the monostable multivibrator 20 would result in such a changeover). The QRS signal triggers the bistable multivibrator 19 back, before the output $\bar{A}$ of the monostable multivibrator 20 becomes negative, after expiry of the 200 msec. The time constant of the monostable multivibrator 20 is therefore so dimensioned that the delay interval (approximately 170 — 220 msec) is in every case longer than the time interval between stimulation and change-over of the bistable multivibrator by the QRS pulse, if produced.

It is advisable to set the duration of the pulses supplied at the output $A_2$ of the pulse generator 10 to be longer than the pulse duration at the output $A_1$, in order that it may be ensured that a pulse is still applied to the input $I_2$ of the bistable multivibrator 19 when a return pulse which might be triggered by a stimulation pulse and which might produce the erroneous impression that a QRS pulse is being supplied, has already decayed at the input $I_1$ of the multivibrator 19. The increase of the pulse duration to for example 10 msec at the output $A_2$ of the pulse generator can readily be effected by connecting a capacitance into the circuitry of the generator.

The illustrated heart pacemaker can readily be modified so as to be a demand pacemaker. For this purpose, it requires only the introduction of a feedback line 25 (shown in broken lines in the drawing) between the output $A_4$ of amplifier 18 and a control input of the pulse generator 10, and of a feed line 26 which is connected to a positive battery voltage of the pacemaker battery and contains a resistance 27 whose value is so adjusted at for example 30 M $\Omega$ that, even in the event of relatively long stimulation pauses, the voltage at the charging capacitance 15 cannot fall off to any noteworthy degree. The feedback line 25 ensures that the pulse generator 10 is always switched into operation if at the probe 17 no QRS signal indicating heart action is received.

It will be appreciated that the entire electronic portion of the pacemaker may be encapsulated in a casting composition, such as for example epoxy resin or silicone rubber. The expression "QRS pulse" as used herein extends to what is sometimes termed the "QRS complex".

WHAT WE CLAIM IS:—

1. An implantable heart pacemaker operable with a predetermined maximum battery voltage, comprising pulse-generating circuitry for supplying electrical stimulation pulses to stimulate heart action, a detector for sensing whether heart action is stimulated by successive stimulation pulses, and pulse-control circuitry arranged to control the pulse-generating circuitry, in dependence upon the detector so that, if successive stimulation pulses each stimulate such heart action, such successive pulses are supplied at respective pulse voltages which are successively less, but so that if one of the stimulation pulses fails to stimulate such heart action within a predetermined period immediately following the supply of that one pulse and ending before the next stimulation pulse is supplied, the said next stimulation pulse is supplied at a pulse voltage greater than that of the said one of the stimulation pulses by an amount which, whilst sufficient for the said next stimulation pulse to stimulate such heart action, is small in relation to the said maximum battery voltage.

2. A pacemaker as claimed in claim 1, wherein the said amount is in the range from 0.1 to 0.5 volts.

3. A pacemaker as claimed in claim 1 or 2, wherein the pulse-generating circuitry comprises a battery-operated pulse generator adapted to produce a pulse train determining the rate at which the said electrical stimulation pulses are supplied, a pulsing capacitance successive discharge of which is adapted to produce the said electrical stimulation pulses, discharge control means connected to receive the said pulse train and adapted to bring about successive discharge of the said pulsing capacitance at a repetition rate determined by the pulse repetition rate of the said pulse train, a charging capacitance which is of greater value than the said pulsing capacitance and is connected to charge the said pulsing capacitance, and charging means for charging the said charging capacitance.

4. A peacemaker as claimed in claim 3, wherein the value of the said charging capacitance is in the range from 20 to 100 times

greater than the value of the said pulsing capacitance.

5. A pacemaker as claimed in claim 4, wherein the value of the said charging capacitance is in the range from 40 to 80 times greater than the value of the said pulsing capacitance.

6. A pacemaker as claimed in claim 3, 4 or 5, wherein the said detector is adapted to sense QRS pulses and wherein the said pulse-control circuitry includes current blocking means connected between the said charging means and the charging capacitance, the current blocking means being controlled by the said detector so as to inhibit charging of the said charging capacitance if a QRS pulse is sensed by the said detector within the said predetermined period immediately following the supply of each successive electrical stimulation pulse by the pacemaker but to permit such charging for a controlled period of time in the event that no QRS pulse is sensed within the said predetermined period.

7. A pacemaker as claimed in claim 6, wherein the discharge control means are adapted to bring about successive discharge of the said pulsing capacitance at a repitition rate equal to the pulse repetition rate of the said pulse train.

8. A pacemaker as claimed in claim 7, wherein the current blocking means comprise a monostable multivibrator and a bistable multivibrator that respectively have inputs connected to receive the said pulse train and respectively have outputs connected to inputs of an electronic gate of the current blocking means, the electronic gate being arranged to control the connection of the said charging means to the said charging capacitance in dependence upon input signals which the gate respectively receives at the said inputs thereof from the multivibrators when the pacemaker is in use, the bistable multivibrator having a further input connected so as to receive a pulse every time a QRS pulse is sensed by the said detector.

9. A pacemaker as claimed in claim 8, wherein the detector comprises a receiver for receiving such QRS pulses and, connected with the receiver, an amplifier for delivering the received QRS pulses in amplified form at an output thereof.

10. A pacemaker as claimed in claim 9, wherein the said further input of the bistable multivibrator is connected to the said output of the amplifier.

11. A pacemaker as claimed in claim 8, 9 or 10, wherein a resistance is connected between the said charging capacitance and the electronic gate in such a manner that the charging capacitance is charged through the said resistance when the pacemaker is in use.

12. A pacemaker as claimed in any one of claims 8 to 11, wherein the monostable multivibrator has a time constant in the range from 150 to 250 msec.

13. A pacemaker as claimed in claim 12, wherein the monostable multivibrator has a time constant in the range from 170 to 220 msec.

14. A pacemaker as claimed in any one of claims 3 to 13, being a demand pacemaker, wherein the charging capacitance is additionally connected to the said charging means through a high resistance and the pulse generator is connected so that the operation thereof is controlled in dependence upon whether or not successive QRS pulses are respectively sensed by the detector within the said predetermined period immediately following the supply of respective successive electrical stimulation pulses by the pacemaker.

15. A pacemaker as claimed in claim 14 when read as appendant to claim 9 or 10 or to claim 11, 12 or 13 when read as appendant to claim 9 or 10, wherein the said output of the amplifier is connected *via* a control line to a control input of the pulse generator.

16. A pacemaker as claimed in claim 14 or 15, wherein the said high resistance is of the order of tens of megohms.

17. A pacemaker as claimed in claim 15, wherein the said high resistance is substantially 30 megohms.

18. An implantable heart pacemaker, substantially as hereinbefore described with reference to the accompanying drawing.

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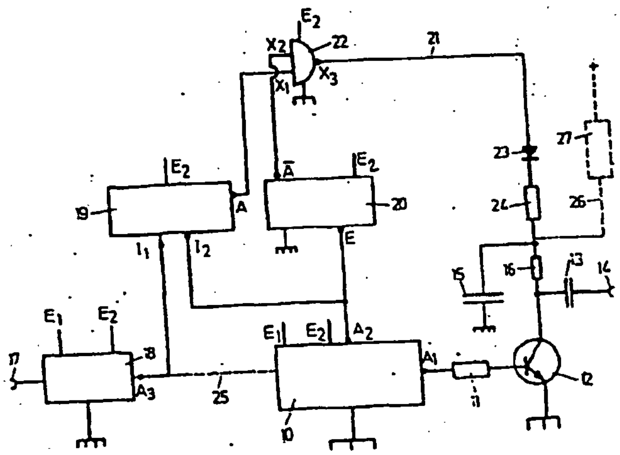


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